Revised June 2015

I. DESCRIPTION OF INTERVENTION - HIV TESTING IN HEALTHCARE SETTINGS

HIV screening in healthcare settings is a public health intervention intended to increase awareness of HIV status in general as well as to identify undiagnosed HIV infections among patients (including pregnant women) in healthcare settings. The primary goal is to find patients who are infected with HIV but are unaware of their status. Further, HIV screening programs should make every effort to link persons with HIV infection to clinical and HIV prevention services. This protocol is based in part on the Centers for Disease Control and Prevention's *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings* (MMWR 2006; 55 (No. RR-14): [1-17]) and is intended to serve as guidance for healthcare settings partnering with, or supported by, the Louisiana Office of Public Health STD/HIV Program (SHP) to implement HIV screening as part of their routine medical service delivery. In the ideal situation, HIV screening should be conducted utilizing a rapid HIV test so that patients will receive their test results during their initial visit to the healthcare site; allowing those patients who have a preliminary HIV positive test result to be immediately linked into clinical and prevention services.

1. **General Principles of HIV Screening:**
   - All patients between the ages of 13 and 64 should be screened for HIV at least one time after the patient is notified that testing will be performed and unless the patient declines (opt-out screening).
   - Persons at risk for HIV infection should be screened for HIV at least annually.
   - Current Louisiana law does not require written consent for HIV testing but patients should be notified that HIV testing will be part of their medical care and given information about HIV testing and transmission. General consent for medical services is considered sufficient to encompass consent for HIV testing.
   - HIV prevention counseling is not required with HIV diagnostic testing or as part of HIV screening programs in healthcare settings but patients who are interested should be offered or referred to prevention counseling services and all patients should have an opportunity to ask questions about HIV testing and how the virus is transmitted.

2. **Principles of HIV Screening for Pregnant Women:**
   - HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women.
   - All pregnant women should be screened for HIV after the patient is notified that testing will be performed unless the patient declines (opt-out screening).
   - Current Louisiana law does not require written consent for HIV testing but patients should be notified that HIV testing will be part of their medical care and given information about HIV testing and transmission. General consent for medical services is considered sufficient to encompass consent for HIV testing.
   - Repeat screening in the third trimester is recommended in areas of the state with elevated rates of HIV infection among pregnant women (see SHP annual and quarterly surveillance reports).

II. GENERAL REQUIREMENTS FOR HIV TESTING AT PARTNERING HEALTHCARE SITES

1. **Establish Appropriate Testing Area(s):** Rapid HIV testing must also be conducted in locations that will assure optimal accurate processing and reading of each test. All rapid test sites must provide adequate lighting, temperature control, testing surface, confidentiality, and counseling area(s).

2. **Register All HIV Testing Locations:** Healthcare testing sites must register both fixed and mobile sites through the SHP Testing Supervisor using the Site Registration Form (see Attachment 1). A SHP staff person will visit each potential site to determine if it is appropriate for HIV screening activities. SHP will assign a unique site number and mail a certificate of approval for HIV testing back to the requesting site once the registration process is complete. OPH Parish Health Units have already been registered with SHP.
3. **Register Rapid Testing With CLIA:** Each testing site is required to obtain a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver to conduct waived rapid HIV antibody testing or add the specific rapid HIV test(s) that will be used to the site's current CLIA registry. The OPH Parish Health Units have already been registered to operate under SHP's CLIA Waiver Certificate and do not need to take any additional steps to be in compliance with CLIA requirements.
4. **Use CLIA Waived Rapid HIV Tests:** SHP recommends the use of (and in some cases may provide) rapid HIV antibody tests that have been classified as "CLIA waived" tests. CLIA deems waived tests as being easy to use and the possibility of obtaining inaccurate results is very small. Additionally, CLIA-waived tests can be administered and results given at the point of care for patients (during intake, in the examination room, etc.), which will increase the likelihood that patients will accept HIV screening as a part of their routine health care.
5. **Maintain Appropriate Supplies:** Healthcare test sites may be supplied with the OraQuick Advance, Uni-Gold Recombigen, Clearview Complete, or INSTI rapid HIV testing devices – all technologies are single-use, qualitative immunoassays to detect antibodies to HIV. All test sites must develop a system to oversee the storage of test kits, reagents, and controls as required by the manufacturer and to ensure that, when outdated, they are properly disposed of.

    - The OraQuick ADVANCE Rapid HIV-1/2 Antibody Test consists of:
        - A single-use testing device and solution vial
        - A reusable test stand, and
        - Disposable single-use specimen collection loops.
    - The Uni-Gold Rapid HIV-1/2 Antibody Test consists of:
        - A single-use testing device
        - A multi-use wash solution bottle (5.0ml)
        - Disposable pipettes for use with venipuncture whole blood and when running controls, and
        - Disposable fingerstick sample collection and transfer pipettes for use with fingerstick whole blood
    - The Clearview Complete Rapid HIV-1/2 Antibody Test consists of:
        - A single-use testing device
        - A lancet
        - A bandage for use after fingerstick
    - The INSTI Rapid HIV-1 Antibody Test consists of:
        - A single-use testing device
        - Three vials of solution
        - A lancet
        - Alcohol prep pad
    - Additional supplies needed:
        - OraQuick, Uni-Gold, Clearview, or INSTI controls
        - Disposable absorbent workspace covers
        - Biohazard waste disposal bags
        - Latex/polyurethane/nitrile gloves
        - Sharps Container (for blood specimen testing only)
        - Disposable Lancets (for blood specimen testing only)
        - Thermometers (one for the storing area, one for the refrigerator, one for mobile sites)

- Timers
- 10% bleach solution or FDA approved disinfectant
- Standard phlebotomy equipment for confirmatory testing
- Appropriate transportation supplies for confirmatory specimens (e.g., mailing bags and specimen canisters)
- HIV Test forms – Part 1 and Part 2 (and Lab Requisition Form for sites sending specimens to the Louisiana Public Health Laboratory)

Testing supplies will be provided by the STD/HIV Program as specified in the Memorandum of Understanding negotiated between SHP and the healthcare test site. Test sites may be required to obtain certain items at their own expense. Testing sites will not be provided additional funds for supplies or phlebotomy services. Up-to-date documentation of testing (including HIV Test forms) must be submitted to the STD/HIV Program before additional supplies will be sent to the test site (see required documentation). Maintaining appropriate testing supplies in inventory is the responsibility of each healthcare test site.

6. **Consider Age Before Testing Patients:** HIV testing supported through partnerships with SHP can be offered to individuals age 13 and older without parental consent – parents must be present and give consent before any child age 12 or younger is tested for HIV - except in cases of suspected perinatal HIV exposure when the mother will not consent for an HIV test in accordance with Louisianan HIV testing laws. Additionally, healthcare test sites should always verify the appropriate age range approved by the United States Food and Drug Administration (FDA) when conducting any rapid HIV test. Age limitations will be covered during the testing staff's training provided by SHP and are also listed in the manufacturers' instructions, which are included in each box of rapid HIV test kits.
7. **Assign a Quality Assurance Coordinator:** Healthcare test sites must identify, in writing, the name of their designated Quality Assurance Coordinator using the Quality Assurance Coordinator Registration Form (see attachment 2). This is typically the same person identified to CLIA as the laboratory director, such as an ED Director, Lab Director, Head Nurse, Prevention Manager, etc. The site's rapid testing Quality Assurance Coordinator will be responsible for informing other testing staff on updates and/or revisions to manufacturer's instructions and the State of Louisiana HIV Testing Quality Assurance Protocols as well as any recalls that may occur on testing supplies. The Quality Assurance Coordinator is also responsible for ensuring his/her agency is in compliance with the quality assurance protocol including the proper use, storage and documentation of rapid testing devices/activities. Quality Assurance Coordinators must be fully trained on the rapid testing device(s) being used at his/her agency.
8. **Conduct Worker Competency Assessments:** Although not required by CLIA for sites operating waived testing devices, it is good laboratory practice and highly recommended that partnering test sites develop a system to continually assess the ability of HIV testing staff to operate testing devices correctly, interpret results accurately, and work safely following universal precautions. SHP has provided an HIV Testing Competency Assessment for Health Care Testing Staff (see attachment 10) which sites are encouraged to use for evaluating the competency of their staff prior to conducting testing with patients and annually thereafter.
9. **Run Controls Appropriately on Test Devices**: The respective kit controls (OraQuick, Uni-Gold, Clearview, and INSTI) verify that the rapid HIV antibody test is working properly and that users are able to properly administer and interpret the test results. Kit Controls must be run under the following circumstances:
    - Each newly trained staff prior to performing rapid testing on patient/patient specimens
    - When opening a new test kit lot (lot numbers are printed on each box and device package)
    - Whenever a new shipment of test kits is received

- If the temperature of the test kit storage area falls outside of the acceptable temperature range for that type of test kit
- If the temperature of the testing area falls outside of the acceptable range for that type of test kit
- Prior to using test kits at remote locations (when the test kits are used away from the area where they are stored, e.g., mobile vans, outreach testing, prisons/jails, drug treatment centers)
- At periodic intervals as dictated by the partnering site (sites may run controls more frequently than specified above but must at least meet the above minimum requirements for running controls).

If the results of any one of the control tests do not match the expected result, rerun all controls. If the repeated control test run produces unexpected results, do not use any tests from that entire lot number and notify the SHP Testing Supervisor immediately. Also, each rapid test device contains a built in control feature that demonstrates assay validity. A reddish-purple control line (or dot in the case of INSTI) should appear in the area labeled "C" or "Control" depending on the specific device being used. The control line must appear in order for the respective test to be valid, whether or not the test line suggests reactivity. Test results are considered "invalid" when:

- No reddish-purple line or dot appears next to the area labeled "C" or "Control"
- A red background in the result window makes it difficult to read the result after the appropriate processing time has elapsed.
- If any of the lines are not inside the appropriate control or test line areas.
- The sample well is not completely red after adding a blood specimen (Uni-Gold tests only).

10. **Appropriately Dispose of Testing Equipment:** All used HIV testing supplies should be disposed of in biohazard waste material bags and/or sharps containers and be disposed of in accordance with state and site-specific regulations for disposal of infectious waste. Control specimens and all blood products should be handled in accordance with universal precautions and the manufacturer's instructions. Proper disposal of biohazardous waste materials will be the responsibility of the site conducting HIV testing. Shipping or transporting of used HIV testing equipment outside of the test area is prohibited, unless stored in a closed biohazard waste container.
11. **Submit Completed HIV Test Forms Weekly:** HIV Test Forms must be completed in their entirety and submitted to SHP weekly. Healthcare test sites will not be provided additional supplies if HIV Test Forms are not completed accurately and submitted to SHP on at least a weekly basis.
12. **Cooperate with OPH Disease Intervention Specialists (DIS) and Field Epidemiologists (Epis):** All partnering sites are required to cooperate with efforts by Office of Public Health DIS and Field Epis to collect information on patients who test HIV positive. This includes confirming and/or updating current address and phone numbers for the purpose of disease investigation and partner services. Any special circumstances or additional information surrounding these activities should be noted to the DIS.
13. **Request Assistance As Needed:** Healthcare test sites are encouraged to request assistance from SHP as the need may arise. SHP can assist with developing testing protocols, establishing appropriate referral networks, and providing a number of other technical assistance trainings related to implementing HIV screening. SHP staff can be in attendance during the site's first day of HIV screening to help resolve logistic or technical problems, if the site requests this assistance.
14. **Follow This Protocol:** Failure to follow this protocol may result in a discontinuation of partnership/support between the testing site and SHP. Protocol violations witnessed by or reported to SHP will be discussed with the testing site immediately. Recommended corrective action, if any, will be documented and submitted to the testing site and SHP Testing Supervisor.

III. General Requirements of Testing Staff

1. **Complete HIV Training Requirements:** All healthcare professionals conducting HIV screening in partnership with SHP must complete a brief training on HIV testing and be assigned a unique HIV Testing Staff ID Number. The HIV Testing for Healthcare Professionals training includes specific instruction on the type of HIV test staff will be using and training on strategies for delivering HIV test results and making referrals to other services. The SHP Training Coordinator will schedule these trainings as needed to satisfy this requirement and provide healthcare testing staff with certificates of completion containing their HIV Testing Staff ID Number.
2. **Complete Universal Precautions Training:** All healthcare professionals conducting HIV screening using blood specimens (or blood products) must be trained on universal precautions for the prevention of transmission of HIV and other bloodborne infections, safe work practices, and disposal of biohazardous materials. It is expected that healthcare test sites will provide this training to their own employees/staff.
3. **Follow Manufacturer's Instructions:** Testing staff must read and follow the manufacturer's instructions provided by the manufacturer of the rapid test device they will be using. Not following the manufacturer's instructions may result in inaccurate test results.
4. **Avoid Rapid Testing Patients Who Know They Are HIV Positive:** Patients who identify themselves as HIV positive should not be retested with a rapid test. Individuals infected with HIV-1 and/or HIV-2 who take antiretroviral medication or who have severely damaged immune systems may produce false negative rapid test results. Self identified HIV infected persons who need documentation of their HIV status should be offered a conventional immunofluorescence assay (IFA) or Western Blot (WB) HIV test and should be referred to case management and medical care.

IV. SPECIFIC REQUIREMENTS OF TESTING STAFF - Before Testing A Patient

1. **Obtain Informed Consent:** Separate written consent is not necessary for HIV testing but all patients should be notified at some point during their visit (and prior to being tested) that HIV testing will be conducted as part of routine procedure. Patients should be given information about HIV transmission and the meaning of HIV test results prior to being being tested. Patients must have the ability to decline HIV testing (to opt-out).
2. **Inform Patients of Partner Notification Policies:** All patients must be informed of the importance of notifying sex and/or needle sharing partners should their test results be reactive/positive for HIV. A discussion of Partner Services should be provided before testing begins for all patients and a more detailed discussion should be conducted after providing a patient with a reactive (preliminary positive) rapid test result. Testing staff should record patients' contact information on the HIV Test Forms Part 1 to facilitate referral follow up and partner services. Testing staff must discuss the Louisiana Office of Public Health policy to contact all persons testing confidentially and reactive to HIV regarding Partner Services.
3. **Offer Patient the Available Options for HIV Testing:** Patients must be offered the option of anonymous or confidential HIV testing in accordance with Louisiana Testing Law (RS:1300.12). If anonymous testing is not available at the testing site, the patient should be referred to a site that is able to provide anonymous HIV testing upon request. Confidential testing is strongly encouraged to facilitate the entry into follow-up medical services for individuals who have been identified as HIV infected and should be encouraged for all confirmatory testing. Patients should also have the choice of which type of specimen (oral fluid, fingerstick whole blood, venipuncture whole blood, etc.) will be collected for HIV testing (according to which HIV testing technologies are in use at the testing site) and when test results will be given (same day or at a later return visit).

4. **Discuss possible test results for the type of HIV test being conducted:** Testing staff should discuss all of the possible test results and the applicable follow-up procedures for the type of HIV test being used with each patient prior to collecting a specimen for testing.
5. **Provide appropriate subject information pamphlet if conducting a rapid HIV test:** The FDA requires that all patients having a rapid HIV test, receive the "Subject Information" pamphlet produced by the manufacturer of the rapid test device being used prior to having a specimen collected for testing. These pamphlets are included in each box of rapid testing kits. Contact the SHP Training Coordinator for additional copies of these pamphlets.

V. SPECIFIC REQUIREMENTS OF TESTING STAFF - WHILE TESTING A PATIENT

1. **Complete HIV Test Form – Part 1: A**ll applicable sections of HIV Test Forms – Part 1 should be completed for all clients who receive an HIV test. It is recommended that Part 1 be filled out while the HIV test is processing in order to keep the patient occupied and possibly lower his/her anxiety about the pending test results.
2. **Conduct Other Medical Exams/Services:** After completing the appropriate sections of the HIV test Forms – Part 1, testers should initiate other health care services as needed/available. It is preferable to conduct these activities while the HIV test is processing if possible.
3. **Provide Support:** Testing staff may give patients condoms, other harm/risk reduction tools and/or HIV prevention literature as appropriate and available.
4. **Assess patient readiness to receive result:** Testing staff should check with patients prior to interpreting/reading the HIV test results to ensure that the patient still wishes to receive their test results at that time. If the patient does not wish to receive the test result at that time, the tester should schedule a follow-up appointment for the patient to receive the test results (the tester should document the test results in the patient's chart for later use).

VI. SPECIFIC REQUIREMENTS OF TESTING STAFF - AFTER TESTING A PATIENT

1. **Interpret/Read and Deliver Test Result:** After interpreting or reading the HIV test result, immediately deliver the result to the patient and ensure he/she understands the meaning of the test result.
2. **Proceed with Patient in the following ways based on the test results:**

If Result is Negative/Nonreactive:

- Accurately communicate results with patient
- Allow time for emotional response. Do not rush the patient into conversation.
- Ensure the patient understands what the result means.
- Assess patient concerns.
- Recommend a follow up time for patient to be retested for HIV based on section I guidelines.
- Assess the patient's need for other referrals
- Provide condoms and literature as deemed appropriate.
- Document negative result on HIV Test Form – Part 1.

If Result is Positive/Reactive (screening or confirmatory):

- Accurately communicate results with patient (if a rapid test, inform the patient that the result shows signs of HIV antibodies and a confirmatory test must be done to be sure.)
- Allow time for emotional response. Do not rush the patient into conversation.
- Ensure the patient understands what the result means.
- Assess patient concerns.

- Collect confirmatory specimen if rapid test was conducted: Patients who have a reactive/preliminary positive rapid HIV test result must be given a follow-up confirmatory test unless they decline and be provided with referrals to early intervention medical services during the delivery of their preliminary positive result. If possible, blood specimens should be collected for confirmatory HIV testing. All HIV testing sites are expected to inform 100% of patients of their reactive test results.
- Complete Appropriate Lab Requisition: The appropriate form/documentation should be completed to ensure that the results of the confirmatory test will be traceable to the patient being tested and that results will be available as soon as possible. For sites sending specimens to the Louisiana public health laboratory, the Louisiana Laboratory Requisition Form must be completed and mailed along with the confirmatory specimen.
- Emphasize the importance of taking the same precautions as a person who may have a confirmed HIV positive test result in terms of contracting additional infections and potentially transmitting the virus to others.
- Negotiate additional referrals with patient, including potential medical and partner services referrals.
- Complete HIV Test Form – Part 2 with the patient.
- Set appointment for patient to return for confirmatory test results.
- Provide condoms and literature as deemed appropriate.

If Rapid Test is Invalid:

- Explain that no result is available due to a malfunction with the testing process.
- Assess patient concerns and emotional response.
- Quickly assess the testing environment for appropriateness for the specific rapid test being used (ensure operating temperature is acceptable, test kits are not expired, etc.)
- Repeat the test using a new rapid test device or conduct a conventional test (OraSure or blood draw) if the patient refuses an additional rapid test.
- Provide condoms, other harm/risk reduction tools and appropriate literature.
- BEFORE TESTING ANOTHER PATIENT: Run external controls to ensure testing devices are working correctly and assess quality assurance documentation paying attention to temperature and control logs. Discontinue testing if controls do not pass or testing environment is inappropriate and complete documentation of this problem on all logs.

If Discordant Result (Reactive rapid test and indeterminate or negative confirmatory test)

- Assess patient concerns.
- Establish plans for follow-up testing to occur 4 weeks after the initial preliminary positive result. It is highly recommended and inline with CDC rapid testing protocol that follow-up confirmatory testing be conducted with a blood specimen.
- Provide condoms, other harm/risk reduction tools and appropriate literature.
- Complete Discordant Case Report Form and submit to SHP.
- Notify the SHP Testing Supervisor immediately.

IV. REQUIRED DOCUMENTATION

All documentation/forms related to HIV testing that are designated "Submit to SHP" in the header should be mailed to the following address:

OPH Testing Department
1450 Poydras St., Suite 2136
New Orleans, LA 70112.

To insure proper confidentiality measures, forms containing identifying patient information must be enclosed in two envelopes and marked "confidential" on the inside envelope. Testing information should be addressed to the Office of Public Health without any reference to "HIV" and/or "AIDS" in either the sender's address or the recipient's address. Forms that are hand delivered will not be accepted unless they are enclosed in two envelopes and properly addressed.

Following is a description of documentation that must be maintained and/or submitted to SHP along with the submission timeline where applicable.

1. **Maintain on site: The following documentation should be kept on file at testing sites for at least 3 years.**

   a) **Test Device Temperature Log** (Attachment 3): Documentation of storage room temperature must be recorded daily for test kits.
   b) **Control Kit Temperature Log** (Attachment 4): Documentation of control kit storage temperature must be recorded daily for control kits.
   c) **Daily HIV Testing Log** (Attachment 5): All rapid tests conducted must be recorded on a daily test log. These logs are kept in agency files and may be reviewed by SHP at any time.
   d) **Control Kit Log** (Attachment 6): All control tests run at the testing site must be logged on the Control Log and signed by the Quality Assurance Coordinator. Any corrective action taken as a result of control testing must be documented on this log.
   e) **HIV Testing Competency Assessment for Health Care Testing Staff** (Attachment 9)**:** Internal monitoring of the quality of test processing for individuals involved in rapid HIV testing activities may be conducted using this form. It is highly recommended that all HIV testing staff be observed at least once per year by a supervisor or the designated Quality Assurance Coordinator to ensure quality HIV testing services are maintained. Competency assessments should be kept on site in employee files.

2. **Weekly Submission: The following documentation must be sent to SHP at least weekly.**

   a) **HIV Test Form – Part 1:** Part 1 of the HIV Test Form should be completed for every patient who receives an HIV test that is in anyway supported by SHP. Instructions for completing the HIV Test Forms are available in a separate document and may be requested from the SHP Clinical Testing Promoter.
   b) **HIV Test Form – Part 2:** Part 2 of the HIV Test Form should be completed after the patient receives the confirmatory positive HIV test result. Instructions for completing the HIV Test Forms are available in a separate document and may be requested from the SHP Training Coordinator.

3. **As needed**: S**ubmit the following documentation as needed.**

a) **Supply Order Form (**Attachment 7): A Supply Order Form should be completed and faxed to SHP when supplies are needed but not more often than once a month unless an emergency order is needed. Please allow at least 4 weeks for normal processing or write "emergency order" across the top of the form for special circumstances when an order is needed immediately to continue testing. Sites will be contacted about all emergency orders to determine why normal ordering was not sufficient for maintaining testing supplies and an inventory control plan may be negotiated with the site to avoid additional emergency supply situations.
b) **HIV Testing Site Registration Form** (Attachment 1): Prior to conducting HIV testing activities at any site, a Site Registration Form must be completed and submitted to the SHP Clinical Testing Promoter. All HIV testing sites must be approved by SHP prior to the start of any HIV testing activities. Please allow up to four (4) weeks for approval of each site. A copy of this form should be kept on site.
c) **Discordant Test Report** (Attachment 8): All confirmatory test results that are negative or inconclusive must be followed up with a Discordant Test Report.

V. DEFINITIONS OF KEY TERMS

Healthcare HIV Testing Sites – refers to clinics, agencies or organizations that offer HIV testing in cooperation or partnership with SHP in addition to other healthcare services but who do not receive monetary funding from SHP to do so. Healthcare test sites will have usually competed for and been awarded support (test kits, technical assistance, lab services, etc.) from SHP through a request for strategic partnerships process.
HIV Testing – Performing/conducting an HIV test.
HIV Testing Staff – (also referred to as tester, worker or staff) this is a person who conducts/administers a rapid HIV test or the person who collects the specimen for HIV testing when the actual HIV test occurs at a lab or remote location. HIV testing staff generally conduct HIV testing for screening purposes and may not be trained to conduct HIV Prevention Counseling.
HIV Testing Staff ID Number – a unique identifying number assigned to every HIV testing staff after he/she completes the required training on HIV screening protocol and rapid HIV testing.
HIV Screening – Performing an HIV test for all persons in a defined population.
Informed consent – A process of communication between patient and provider through which an informed patient can choose whether to undergo HIV testing or decline to do so. Elements of informed consent typically include providing oral or written information regarding HIV, the risks and benefits of testing, the implications of HIV test results, how test results will be communicated, and the opportunity to ask questions.
Opt-out HIV Screening – Performing HIV screening after notifying the patient that 1) the test will be performed and 2) the patient may elect to decline or defer testing. Consent is inferred unless the patient declines testing.